Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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SESSION 2: REFLECTING ON THE PAST, PRESENT, AND FUTURE IMPACT OF NATIONAL BIOETHICS ADVISORY BODIES

DR. WAGNER: We are continuing our conversation on the impact of national bioethics advisory bodies. And… as our panel grabs their seat, we will follow the same format this afternoon. We will work through our panelists. Please…take your time. We will do the same process, introduce each of you individually and have you make your remarks. We'll have some conversation, and then we're going to invite the prior panelists also to join us for the final session of the day.

DR. WAGNER: I have the pleasure first, Tom, of introducing you. I'll speak slowly, so you can get your materials together. Tom Beauchamp is known to us. He is Professor of Philosophy, a Senior Research Scholar in the Department of Philosophy and Kennedy Institute of Ethics at Georgetown. He has published extensively on ethics of human subjects research, the place of universal principles, and the rights of biomedical ethics, Hume, and – excuse me, Hume and the history of modern philosophy, and business ethics.

DR. WAGNER: He presented to our 12th meeting about the application of Belmont Principles to pediatric research. In 2011, he was given a Lifetime Achievement Award for Excellence in Research Ethics by the research ethics and compliance professional organization Public Responsibility in Medicine and Research.

In 1975, he joined the staff of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, where he actually was a principal author of the Belmont Report.

It's wonderful to have you back, Tom. Thank you for joining us today. The floor is yours.

DR. BEAUCHAMP: Thank you.

DR. WAGNER: Please turn the microphone on.

DR. BEAUCHAMP: Okay. Alright. Now, I know what I'm doing. I have the wrong glasses on to read the timer, actually, but that's okay. I think I can do it.

DR. BEAUCHAMP: I'll talk primarily about the impact of the work of the National Commission where I was assigned the task of drafting the Belmont Report. I'll try not to overlap too much with Patricia King, who of course was a commissioner on that Commission.

My job was to draft; the commissioner's job was to critique, and this went on and on for month after month. We met every month. And I guess it took two years to get through the Belmont Report.

DR. BEAUCHAMP: Then, I'll later mention some incomplete features, I think, of Belmont that might profitably be pursued by a national advisory board. So, about the first half, I'll talk about impact, where I know something about impact that you might find interesting, and the second part about remaining things that might be done – following up from more or less the theoretical areas of bioethics that I find interesting, and I think might need further investigation.

The Commission was established in 1974 by Congress with a charge to identify ethical principles that should govern the conduct of research involving human subjects, which the Belmont Report does, I believe. In fact, it gives almost all of the space to principles.

DR. BEAUCHAMP: However, there was another congressionally mandated goal of the Belmont Report, which was to distinguish the boundaries between the accepted and routine

practice of medicine and biomedical and behavioral research. The report also does that. I cannot claim credit for the drafting of that. That was done by Bob Levine [Robert Levine].

The National Commission published 17 reports and appendix volumes. Most focused on uses of vulnerable populations. Its more than 100 recommendations for reform went directly to the Department of Health, Education, and Welfare, and many were codified in federal regulations.

DR. BEAUCHAMP: Belmont exhibited the basic principles put to work in most of these reports. In other words, what you find in Belmont is the basic principles, and then you go to the other reports and you'll see how these basic principles are being appealed to, despite what Al Johnson and Stephen Toulmin said, which is that the principles are not much appealed to in these reports. But, at least, that is my reading of it.

The Belmont Report is, of course, especially well-known for what has come to be called the Belmont Principles. There was a general conception that went with the Belmont Principles that I think is somewhat overlooked at times, and that is, the whole idea of having principles was to see how they are applied, in what regions are they applied.

DR. BEAUCHAMP: And part of the reason for the selection of the principles of respect for persons, beneficence, and justice is that each applies in a certain area that was of interest to the Commission. So respect for persons applies to informed consent, beneficence applies to risk-benefit assessment, and justice to the selection of subjects. And that conception is pretty scrupulously kept to, I believe, in the Commission's work.

This conception and the connection between abstract moral principles and applied bioethics I also believe has been enduring. I believe that many people engaged in research ethics today carry more or less this conception with them.

DR. BEAUCHAMP: This particular conception was, I believe, an original idea with the National Commission, although a lot of people will say, "Well, that's just common sense." Well, it may seem now, looking back over almost a half a century, that it's just common sense. But at the time, there was nothing like it, no conception of this sort. So, I think the impact of that general conception, which is the overarching view in Belmont, has been enduring. I think it has been not only influential in the United States, but also abroad, worldwide, although that kind of influence is, I think, much harder to track.

The Belmont Report is also one of the few documents that [have] influenced almost every sphere of activity in bioethics – moral theory and general standards of research ethics, government regulatory activity, bioethics consultation, and even medical practice.

DR. BEAUCHAMP: As Dan Brock has observed, and I quote him, "The Belmont Report had great impact on bioethics because it addressed the moral principles that underlay the various reports on particular aspects of research." I think that's right. Brock is noting the influence of the idea that a body of principles can be used to frame and discuss a wide range of contributions in bioethics to reaching resolution of practical moral problems. In federal regulatory oversight and law, Belmont has at times assumed a near canonical role, and some people I think conceive that it still does.

DR. BEAUCHAMP: The Advisory Committee on Human Radiation Experiments – the Commission that Ruth and Pat [Dr. Patricia King] were on together – noted in 1995 that, and I quote them, "The framework for the regulation of the use of human subjects in federally funded research that is the basis of today's system is undergirded by the three Belmont Principles. The federal regulations and the conceptual framework built on the Belmont Principles became so

widely adopted and cited that it might be argued that their establishment marked the end of serious shortcomings in federal research ethics policies."

Of course, the Belmont Principles found their way into all of the 16 reports of the National Commission, and these became the backbone of applicable federal law in the regulations. From this perspective, as Christine Grady has observed in her 1995 book, and I quote, "Probably the single most influential body in the United States involved with the protection of human research was the National Commission." Do you remember saying that?

(Laughter.)

DR. BEAUCHAMP: The legacy of Belmont may be most enduring in the areas of practice. I use "practice" broadly here, not just clinical practice. Virtually all institutions receiving federal funds for research have subscribed to the Belmont Principles as the basis of their efforts to assess research protocols from an ethical point of view.

DR. BEAUCHAMP: Professional associations, too, have widely recognized the authority and historical significance of the Belmont Principles. And at least one writer – this is Eric Cassell – has argued that the Belmont Principles have, to use his term, "permeated" clinical medicine, which I think is a nice expression for the point of view he is trying to make. The claim that he is making is that the Belmont Principles were a significant force in a broad cultural shift in medicine toward a reworking of the relationship between a doctor and a patient.

Even if the National Commission and the Belmont Report may have succeeded both in resolving some major problems of research ethics and in bringing oversight to the research context as -- I am quoting their historian, David Rothman. Even if he is right in this claim, Belmont to me leaves some moral problems of research ethics in more or less theoretical areas still in need of

further consideration. And I now want to mention as many as three areas, if I can get to the third. The first two take a little longer. So, I'm saying something about what national bioethics bodies might profitably investigate hereafter.

DR. BEAUCHAMP: First, the Belmont Report makes reference to our 'cultural tradition' as the basis of its principles. Early drafts of the report -- these would have been drafts that I made, so I'm partially criticizing myself here Early drafts of the report contained language indicated that the Commission was relying on – and I quote these early drafts, which were there for several months was relying on – "three fundamental principles consonant with the major traditions of Western ethical, political, and theological thought represented in the pluralistic society of the United States."

That was knocked out in favor of the prior language about its being our cultural tradition. Here's my point. I believe it was a mistake to try to express moral principles in terms of particular cultural origins. If I could, I would wipe it out of the Belmont Report right now. I don't know exactly what I would substitute, but I would get that out.

DR. BEAUCHAMP: And especially in terms of differences between Eastern and Western traditions. To say that fundamental principles are culturally bound would be as mistaken as saying that human rights derived from early modern Western political philosophy. Maybe they were elevated at that point, but they certainly don't derive or are particularly applied in that tradition.

To say something like this is to lose sight of the fact that human rights are, by their nature, universally applicable, as are moral principles. The first thing we should say about a

fundamental moral principle is that it is universal, not that it is grounded in something like the major traditions of Western ethical, political, or theological thought.

DR. BEAUCHAMP: In other words, these principles are universally applicable. That's the model that I think should be used. I would very much like to see this perspective thoroughly examined and corrected by a bioethics national advisory body.

What Belmont means by "our cultural tradition", which is the language that is still in the report, is very, very unclear and should never have been in the document. You can see that's my considered opinion, and I would like to see that whole question revisited.

DR. BEAUCHAMP: So, second, the second of the three areas that I'd like to get to that could still need some development: the National Commission was very concerned that it had become too easy in the biomedical world to use utilitarian justifications of research. This came up over and over and over again. The Nazi experiments, Tuskegee, and the Jewish Chronic Disease Hospital cases all seem to have been driven by an undue utilitarian view of social beneficence that justified using human subjects on grounds of benefit to the broader public.

However, despite the Commission's concerns about this, the Commission itself has been accused, and some Commissioners have accused the Commission, of being driven by an all-too-utilitarian view of social beneficence in some of the reports.

DR. BEAUCHAMP: Two Commissioners, Robert Cook and Robert Turtle, sternly criticized the Commission's report on children for an unjustifiable utilitarian justification of research that placed children at undue risk. Whatever the merits of this criticism – and they were a minority, the two were a minority; we rarely had minority reports that were very strong, and theirs were

very strong – to ensure that we appropriately balanced the rights and interests of subjects with those of science and society is, as I see it, the underlying issue here.

I would also note that in at least one case prior to the National – the National Commission is often said to be the first bioethics commission, and I suppose, formally speaking, it was. However, in the Tuskegee Ad Hoc Committee Report, or panel report, more or less exactly the concern that I think I'm expressing here was expressed by Jay Katz.

DR. BEAUCHAMP: This is a really significant problem that you have to get on top of. How can you proceed in science with the justification for what you're doing, and what are the limits that you are able to go? I still think that has not been as well addressed as it should have been and deserves consideration. Belmont certainly does not resolve this problem or even give it serious analysis.

This probably gets a little bit more serious analysis in the children's report, but not adequately there. I wouldn't say no commission has ever given this serious analysis of it. I don't know of one. I'd be happy to be apprised of one if you think it has been done.

DR. BEAUCHAMP: I think this problem needs to be joined to a closer examination of human rights, that it's a human rights theory, and how it's applicable in bioethics, which I consider in an extremely primitive state at the present time.

I also think, and this would certainly be more controversial, that we need to work on animal rights theory and the – and review research practices in the animal world. I personally believe this is unduly neglected and embarrassing in bioethics at the national level that it has not received more attention than it has.

DR. BEAUCHAMP: Here, I want to be a little more positive and reference the Institute of Medicine and National Research Council Report, entitled "Chimpanzees and Biomedical and Behavioral Research", that I'm sure some of you have read. This report breaks ground and makes recommendations and even demands for moral reform of a morally unacceptable situation that needs careful attention.

Its remit was very, very limited, so it's not a broad set of conclusions they reach, but you can – they very nicely lay out the problems and very nicely make suggestions. And it had real impact, real impact that absolutely no one expected to see.

DR. BEAUCHAMP: I believe it's a model of what a national advisory board should aspire to that is to say, taking on the most controversial issues in difficult periods and stating exactly what needs to be done.

In this regard, I want also to reference the ACHRE Report that is to say, the Advisory Committee on Human Radiation Experiments (that Ruth and Pat were on) which cuts against the thinking in various government agencies, and the White House, with whom, of course, that Commission was closely in contact, especially about compensation for injury and also about Presidential apologies for wrongdoing.

DR. BEAUCHAMP: I don't believe that ACHRE actually recommended Presidential apologies, but it recommended apologies. And it turned out that actually, as I read the history, there were two Presidential apologies because the first, which is on radiation, led to the second, which was on Tuskegee. And that was basically the work of this Commission.

So I see this like I see the chimpanzee report. It's ferociously courageous in doing things that they were told that they were not to do. I don't know if you know the history with the

chimpanzee group, but they were told not to pursue the course that they pursued. And I think to some extent ACHRE was a guide in that direction as well.

So, let me see. Let me – having only a few seconds, what do I have, 30, 31 seconds?

(Laughter.)

DR. BEAUCHAMP: Okay. Oh, it's going up. Oh, okay. Alright.

DR. BEAUCHAMP: So, in the end, I think the push for inclusion of subjects in research and broader access to the potential benefits of research, as came, for example, through AIDS activists, has altered the course of research ethics, and arguably, it's an expansion of the scope and use of the Belmont Principles rather than a replacement. But it has certainly reconfigured thinking about research ethics, and I think this problem, too, needs broader attention.

DR. BEAUCHAMP: I conclude by saying that the experience that I had with the National Commission was probably the most exhilarating and intellectually challenging part of my career, and I note that I was advised to turn down the offer of position with the staff by every single philosopher with whom I discussed it. The advice was, "It's just not intellectually demanding enough, and it's not going to help you in your career". You know, applied philosophy as just intellectual laxity, is the idea. Well, never have I been given worse advice.

(Applause.)

DR. WAGNER: Thank you, Tom, and we're glad you didn't take that advice.

Let's move on. Ruth, you're next. She is the Andreas Dracopoulos Director and Philip Franklin Wagley Professor at the Johns Hopkins University Berman Institute of Bioethics. She is a

member of the National Academy of Health and Medicine, a Fellow of the Hastings Center, a Fellow of the American Psychological Association as well.

DR. WAGNER: She has served on numerous national advisory committees and commissions, including the President's Advisory Committee on Human Radiation Experiments, which she chaired. Dr. Faden presented at our second meeting on the Bioethics Commission's charge to address the ethics of synthetic biology. Seems like a long time ago.

DR. WAGNER: She is also co-founder of the Hinxton Group, a global community committed to advancing ethical and policy challenges in stem cell science, and the Second Wave Project, an effort to ensure that health interests of pregnant women are fairly represented in biomedical research and drug and device policies.

We have an opportunity to acknowledge your incredible and transformative contribution in the field of bioethics in light of the fact that you will be stepping down as the founding head of the Berman Institute of Bioethics at the end of June, 20 years after you founded it. Congratulations to you on that.

DR. WAGNER: During your tenure, you have grown the Berman Center into a world leader in bioethics, shaping and reflecting the growth of the field in ways – the ways that we are talking about it today in these meetings. So, we all owe Ruth a debt of gratitude for important work and wish her well as she continues her important work as a bioethics scholar. Let's welcome her this time with a little applause. Congratulations.

(Applause.)

DR. FADEN: Alright. There we go. But I didn't want to waste my seconds on that. I was doing that intentionally.

(Laughter.)

DR. FADEN: Alright. So, Lisa and – thank you. For the record, I am very moved and very much appreciate the acknowledgement. Hard to integrate myself.

Lisa and Nicole reassured me that these could be informal remarks. I have tons of papers in front of me, but don't let that – I am not going to do anything as polished as Tom does. I'm used to that. He is the man I follow.

DR. FADEN: Alright. So, as everyone has acknowledged, my major, most immediate experience with national commissions comes, of course, from chairing – and I feel like I have to say this with emphasis – President William Clinton's Advisory Committee on Human Radiation Experiments, as we might be looking forward to another President Clinton, or not, depending on your point of view. And as has already been acknowledged, Pat King was a fellow traveler with me on that Commission.

Now, we used to call it the Advisory Committee, and then it became known as ACHRE, which is the abbreviation for the initials. It was a Presidential commission. We were appointed by President William Clinton. We were given a remit by executive order, and we had a very specific charge. ACHRE was a singular bioethics commission, singular national bioethics commission.

DR. FADEN: I want to say a few minutes about how ACHRE was different, a few minutes about typologies of presidential commissions. So, as happens – and you may all have already

done a deep dive – I didn't even do the beginnings of a deep dive into the history and nature of presidential commissions until after I was on one and became interested in what they were and how they were structured, and have since thought about that in relation to bioethics commissions more broadly. And then, if we have time, a few minutes about both power and impact. I would love a chance to have a conversation with all of you who have been at this maybe longer than any other group. So, this is a commission that has sat longer and has probably, therefore, more reflections than all of us combined on what works and what doesn't work and the meaning of your whole enterprise.

DR. FADEN: So to begin with, with ACHRE, we were a bioethics commission in a very clear respect, not only in terms of the people who are on the commission and also on our staff, but also what we were charged to do. There had been allegations of wrongdoing, of human rights violations in human radiation experiments, and intentional releases of radiation into the environment. And the President charged us with establishing standards not principles, it's interesting – but standards for evaluating the ethics of what had been done and how we ought to respond to it, since this was with remove. Right? These bounded experiments were thought to have occurred between '44 and '74, 1944 and 1974.

DR. FADEN: There was also a component which was to look at the current state of affairs with research involving human subjects, essentially to vouchsafe to the American public, if possible, that what had happened then couldn't happen now, and then to make recommendations to certainly ensure that what had happened then could not be repeated.

So, that was the part of the Commission that was straightforwardly a bioethics commission. But, it was much more than that from the standpoint of the Administration. From its inception, it became clear to us that we had an additional mission.

DR. FADEN: The news reports that had occasioned the attention to these allegations were not allegations simply that physicians had acted unethically, or that scientists had acted unethically, but also that the government had been complicit, that the government in fact had been responsible for actively deceiving and using members of the American public and others in the interest of national security. And that is what made this such a critical story from the standpoint of an Administration that was the first fully post-Cold War Administration. So the Clinton Administration was the first Administration to begin with the Cold War behind it.

The Administration was committed to openness. This was the notion: they were going to transform the relationship between the citizenry and its public. We were going to change the whole image away from a secret government dominated by clandestine operations, spies and spooks and manipulations of the truth, to something that was quite different. And so that was our remit.

DR. FADEN: Now, in that respect, the Advisory Committee, and this is where I started to get interested later – ACHRE, in types of commissions, was really a kind of crisis commission. It was in the mode of openness or crisis commissions, which are put – instantiated because there is some sort of tragedy, some sort of terrible mistake. Something awful has occurred. Now, this was perceived as something awful that had occurred in the past.

Usually, these are more time-sensitive like a commission established when the accident at Three Mile Island occurred or the Space Shuttle Challenger accident occurred or, more tragically and

more comprehensively, after 9/11 – the 9/11 Commission. The commission is charged to find out what really happened, to see if anyone was at fault, and to make recommendations to fix it. We were that kind of commission in part, which takes me to typologies of types of national commissions.

DR. FADEN: So, one type is this kind of crisis-oriented commission. There is a problem; there is a tragedy that has to be fixed. The government cannot be trusted to investigate itself. This is part of the framework or the political context. You set up an arm's-length commission, properly constituted, that will presumably have the respect and the trust of the American public.

The second kind of – a second kind of commission, and these are not mutually exclusive, are the sort of "political hot potato commissions". The Administration has a problem. Politically, it is very dicey. Maybe it's a matter of partisan politics. And so, you figure out one response is to create a commission to deal with it – base closing commissions, tax reform commissions, Social Security reform commissions.

DR. FADEN: One of my favorite ones when I was looking at this was President John F. Kennedy's Presidential Commission on the Status of Women, which was actually a hot potato commission for him because at that time the Equal Rights Amendment was being pushed, and he didn't want to have anything to do with the Equal Rights Amendment. Apologies to Committee historians who would put it quite differently, but bottom line is, we would park it with a commission. And in fact, Eleanor Roosevelt, for those people who don't recall, chaired that commission, which of course [lent] it extraordinary status and credibility.

DR. FADEN: Another kind of commission, which I think many bioethics commissions might recognize themselves as being a part of, is the kind of commission an Administration or

Congress sets up to seek analysis, advice, and counsel from experts around some technical area, sometimes with public involvement and sometimes with public engagement.

And, for example, President Obama has just set up a commission on enhancing national cybersecurity. So, this is a case where the government wants advice and counsel about a very technical area that is very politically important. So, of course, most commissions have elements of more than one type, and there are other – this is not a mutually exclusive typology.

DR. FADEN: So, we might see some of everything in one commission, or a commission is dominantly one type with an element of something else. I think we were two kinds of commissions. For example, it would be interesting to see what – how you reflect on your own your own structure and function.

All commissions have a role, I think, or a mission of bolstering public confidence in one way or another, trust, integrity, confidence, some relationship of that sort. And there is also, arguably and we cynics would say, a use of any kind of commission to table an issue, to delay it, to back-burner it, to get out from having to deal with it. And we all appreciate that.

So, with these different kinds of commissions in mind, right, I want to make one real quick segue comment to what – the kind of commission we have never had in bioethics and the kind of commission that none of these is.

DR. FADEN: We are also familiar and know about permanent commissions, like the FTC and the FCC, that are permanent features of governments that endure across the Administrations and that have remits and responsibilities that are set up with legal structures that inure them to some extent, protect them from certain sorts of influences and vagaries.

This was exactly – and it's interesting that I am also going to evoke Jay Katz [Jacob "Jay" Katz]. I think it's really hard not to in lots of contexts. Jay argued strenuously during the ACHRE days before and then afterwards, that what we need to have in bioethics was an FTC or FCC-type commission. He was very disappointed with the fact that one of the responses to our commission was to create yet another ad hoc Administration-specific commission. This was a great disappointment to him.

DR. FADEN: And you will remember that, Pat. Part of his big dissent, the only dissent we had was Jay's, and it was in large part, this is ridiculous. We have a perpetuation, a 'begatting' of commissions, and the world doesn't need any more bioethics commissions that are subject to these kinds of -- so this is something I think – I'm sure you've thought about, and very much worth talking about, and it has been kicking around for 20 years. Right?

DR. FADEN: I want to move on to a two-minute comment – or several minutes on power. I think that I certainly didn't appreciate as much as I did afterwards the power that we had as a presidential commission. I came to appreciate the power as we were exercising it only after the fact.

So, I do think that some of the power -- and it would be very interesting to see what you [referring to Patricia King] think after all these many hard years. We were only in business basically 18 months, two years, from beginning to end.

The very fact that you exist, at least the commission exists, I think gives you tremendous – gives anyone in that position a public pulpit that, if used well, can make a tremendous amount of difference. I'll give a few examples from our commission that I think Pat will remember well.

DR. FADEN: We were impaneled or our executive order and charge, required by executive order, that any federal agency respond to any request that we might make for any document that we would want. So, we had this power. We requested all of these documents. I won't go into that process in detail.

But suffice it to say that most of the agencies were very forthright. Some divisions of some agencies were less forthright, and one agency in particular that has three initials that we associate with the Cold War was not very helpful at all. Right?

DR. FADEN: So, the CIA kept saying, "*We don't have any documents. There aren't any. We looked. We're sorry.*" It took us a while to figure out that the way in which we could perhaps move the needle is that, at every one of our public meetings, we gave a report card grading of each of the agencies. Right? And we would report, evaluate so-and-so – so many documents from this agency, so many of this type from that agency, nothing from the CIA. This went on for about three or four months, and then we started getting documents from the CIA. Right?

(Laughter.)

DR. FADEN: Now, it's a power you don't realize you have until you start thinking about it. Similarly, when we moved on to the 'never again' part of our charge, which was to look at the current state of affairs, we decided we wanted to get documents from agencies about currently conducted and reviewed research involving human subjects from NIH, from DoD [U.S. Department of Defense], from VA (U.S. Department of Veterans Affairs), and so on.

DR. FADEN: And the first response was, "*Well, we can't give you those documents*."
"*What do you mean you can't*?"

"*Well, they're -- we can't give you those documents. You're not entitled to those documents*. *You're entitled to the documents from 1944 to 1974*."

"*Well, the executive order,*" we said, "*doesn't say anything about a time limit on the documents*. *We want these documents*."

DR. FADEN: And then we had to go through the same process again. Right? And then eventually the floodgates opened, and it didn't actually take that long, especially with HHS, and certainly with Energy (U.S. Department of Energy). We started getting contemporary documents.

The hitch came when we wanted to get documents from universities. We didn't have subpoena power. So, there we really had no authority. Right? So, we resorted to our report card again, and Pat will remember this. We had a sample of universities, and every month we reported the -- first, all the general counsels -- or I should say all of the universities looking at the university presidents said to us, "We can't give you these. It's not possible. It's not appropriate. We can't have it."

DR. FADEN: And then we started saying, "Here are the list of universities we've requested documents from about the research currently being conducted at the universities to establish that, of course, we're sure everything there is ethical, but, just in case, we want to check." And within a month or two, we had almost all of the universities, and eventually every single university shared their documents with us.

Now, this is what I mean about power. Right? And I didn't – I don't know that we've talked enough in reflecting about national commissions, presidential commissions and power to get – to get clear on what or how commissions should be best structured in order to be able to take

advantage of the power that potentially might exist in the structure and organization of presidential commissions.

DR. FADEN: The last thing, this last minute, I will just say something about impact. Impact is extraordinarily important, and there are many different kinds of impact. I'll put in a plug here. In October, we are going to have a 20th – October 5th – 20th more or less anniversary retrospective on ACHRE to assess whether or to what extent we have had impact and what kind of legacy that commission had. So, I'm going to leave it to others to talk about that.

But, I think in some respects it almost takes 20 years, right, to get a sense potentially of what impact a commission can have. Belmont and the National Commission [were] stunning in the immediacy and the dramatic character of the impact of that commission and its reports.

DR. FADEN: But, if you think about impact in terms of public policy debate, public understanding, actionable recommendations and the extent to which they're adopted, impact more pervasively in terms of legal cases, legislation, policies that go on, and then finally, impact on the field of bioethics, it can take a while to see the fruits of your labor. And I'm sure we'll see many such fruits from this commission. So, thank you.

(Applause.)

DR. WAGNER: Thank you, Ruth.

Our next speaker is Manuel Ruiz de Chávez, President of the Board of Directors at the Mexico National Commission of Bioethics, and Professor of Preventive Medicine and Public Health at National Autonomous University of Mexico.

Dr. Ruiz de Chávez trained as a physician and is a fellow of the Royal College of Physicians of London. He is a member of the Royal Academy of Medicine of Spain. And currently he serves also as [a] representative of Mexico at the Committee on Bioethics of the Council of Europe, UNESCO's Intergovernmental Bioethics Committee.

DR. WAGNER: In recognition of his career in medicine and public service, the Mexican government presented him the 2005 Gerardo Varela (Am I pronouncing that right?) National Award in Public Health, which is stunning and remarkable. Congratulations.

Internationally, Dr. Ruiz de Chávez has represented Mexico's Secretary of Health before the Committee on Bioethics at the Council of Europe. He has also had a national point contact – served as national point contact for the National Council for Science and Technology of Mexico to the European Union in support of Horizon 2020 Projects, which encourage collaborations between Mexican and European scientists.

Welcome, and we are pleased to have you here.

DR. RUIZ DE CHÁVEZ: Thank you very much. I appreciate this invitation, and I am going to use some slides. And I am very happy, and I think it's –

DR. WAGNER: If you will just say – they can be advanced from the back there, I think.

DR. RUIZ DE CHÁVEZ: Well, that will use some of my time.

DR. WAGNER: Yes. Just let us know – there you go.

DR. RUIZ DE CHÁVEZ: But I would like to thank you for this opportunity to present what we are doing and what we would like to do. And as I said, thank you to all of you. I think that I will speak about the evolution of our legal framework.

I should say that, in 1999, it was created, the Commission, as [an] advisory body. But, the formal structure of the National Commission of Mexico, it is in [2005]. It is the National Commission, as the concentrated body, with authority and our own resources – not too much, but at least we can do some things.

DR. RUIZ DE CHÁVEZ: We have a period of reform in the Health Act which now, by law, we have to set up the Hospital Committees of Bioethics, and also the Research Ethics Committee, by law. By the guidelines of the National Commission of Bioethics, this is something important, and now, we have to follow up these committees.

Then, now, we are working to change the structure and the legal framework, and we expect to have a new presidential degree – because we have new attributions, and the law has to reflect it on our structure.

DR. RUIZ DE CHÁVEZ: The other thing is – sorry – that I would like to say that – it's okay – bioethics in the health sector program, I think this is very important, because it plays – bioethics as management and development – in the policy of the universal health system on Mexico – of Mexico. And, if you see, we have to promote respect for dignity and human rights in healthcare. We have to foster ethics, scientific integrity, and protection of human rights in research. And also, it is very important for us that we have to look at the people, to promote the knowledge of bioethics to the citizens. Because sometimes, when I am with people in a social meeting, I say that I am in the bioethics and, "*I'm sorry? Where are you?*"

(Laughter.)

DR. RUIZ DE CHÁVEZ: And I have to speak about what is bioethics.

Then, the next thing is this is a way in which we look at bioethics in Mexico. First of all, the National Bioethics Commission. Then, we have 32 State Bioethics Commissions, and then, the branch, we operate bioethics through the Research Ethics Committees, and also Hospital Bioethics Committees.

DR. RUIZ DE CHÁVEZ: But, it's very important for us to have the links with international organizations, and the National Bioethics Commission as this beautiful presidential commission. And the other is the links that we have with higher education institutions, the academies, for example, the National Academy of Medicine. This is – more or less – we have 31. We are missing one state. But, we have annual meetings with our state commissions, and we look at what is going on around the country.

We have guidelines, and they are independent because we are – they are federal, state, and autonomy, and so on. But, we have to have close connections to interchange programs of bioethics.

DR. RUIZ DE CHÁVEZ: This is our guidelines for Hospital Bioethics Committees. We have already nearly 700 registered committees, but we should have 1,200 committees. But, the most important thing is that if you want to have the certification of the Health Council as a hospital, you need to have the [Hospital] Committee on Bioethics.

The other one is the research ethics committees. As you can see, these both are online and also printed, and we send to the hospitals, and you can ask for it. And it gives you how to set up and how you are able to work.

DR. RUIZ DE CHÁVEZ: The next one is the commission structure. We have the council, the President, the operative structure. You can see we have 5628 ladies and 5828, sorry, colleagues. You'll see it – I think it is very important we have administrative support, but mainly multidisciplinary stuff. We have only four M.D.'s.

This is a council of the National Bioethics Commission and outstanding persons. We change – they change each four years. They are not allowed to relate – to have a relation. And the other thing, which is very important, that most of them are from different fields, different thoughts, and this is a plural approach by ladies and colleagues.

DR. RUIZ DE CHÁVEZ: We had a professor – Jonathan Moreno was here. We have a meeting in some time ago, and this council – our council has this ordinary session. We look at those topics, but we weren't very happy with those outstanding persons that we are dealing about how to strength [strengthen] the commission, at least in Mexico.

This is our venue. This is our new building. It was inaugurated in 2012, and it allows us to develop our work. For example, we have a video conference that we are able to transmit via internet, everything, and we have visual conference with our State Commissions, or with other parts of the world.

DR. RUIZ DE CHÁVEZ: This is the topics that we are dealing with. We give pronouncements and also some assessments in these topics. For example, now, we are dealing with surrogate motherhood and also with our ARTs, end-of-life dilemmas and palliative care, biomedicine and human rights, with the Oviedo Convention – I will talk more – but something very important for us is the research ethics and scientific integrity.

And so you can see other topics as bioethics and marijuana, mental health, emerging medical technologies, and, something which I will speak a little bit more, is bioethics and justice. We work a lot with the legal issues, but also with immigration. Climate change is another concern.

DR. RUIZ DE CHÁVEZ: I think that I have to – these are strategic national links. For example, the National Council for Science and Technology supports all of our activities, you know. We have to present a project, and they give us the research support, the money support.

But, something which I want to show you – this agreement that we have with the National Commissions of Superior Court of Justice of The United Mexican States in order to inform about death with dignity, ARTs, vulnerability, children and women's rights, and data protection, and also informed consent, among others. And we have this part in order to work with judges in order to teach them or to say, this is the state of the art.

DR. RUIZ DE CHÁVEZ: Of course, it is very important to work with the academics and associations in science, medicine, and bioethics. I think that this is – we are working with the Oviedo Convention. We work with the Council of Europe in order that Mexico will join in biomedicine and human rights. It will be first country that will make the accession of the Oviedo Convention.

DR. RUIZ DE CHÁVEZ: Capacity-building for health professionals: We train 1,200 members of the committees, both in research and in the hospital committees. And this is something very important, that we have this course – perhaps you don't have – you are not able to see well, but it was for medical residents on palliative care, for example, and by internet. And even we had a hospital from Nicaragua, and they were dealing with these topics.

DR. RUIZ DE CHÁVEZ: Sorry. I will go – sorry.

DR. RUIZ DE CHÁVEZ: I think that perhaps you know the person which is up of the right. It was the World Congress on Bioethics. Some of you were there. And also we have, for example – we had the Global Summit in Mexico City. And now, it was in Berlin. I met some of you, and we have our video conference. We are – it is the five edition already, and we are very happy because we have people from different countries, from different institutions, with different backgrounds, and obviously, with different approach of bioethics.

We have our library. We are very proud because we are able to provide information. I think that we have the most important information about bioethics in our library, and we provide it for free because of a grant of the National Council of Science and Technology.

This is our gazette. We deal with these topics, and you -- this is in print or also you can get it from online. You can get it now if you have the app.

DR. RUIZ DE CHÁVEZ: And this is our relevant publications. We have the research ethics and integrity in science, which it was a project that the CONACyT [an abbreviation for the National Council of Science and Technology] ask to us to write it and CONACyT give it to all researchers and the evaluators of the projects, and so on.

DR. RUIZ DE CHÁVEZ: And also, you can see the publications of the Global Summit and the World Congress, and this book on Dilemmas on Bioethics.

DR. RUIZ DE CHÁVEZ: Our global scope: I think for us it's very important to be in the Council of Europe, also in UNESCO. But, we work quite a lot with Latin America and Caribe [the Caribbean]. They ask for information, and we support them, and we keep contact. And we are very happy to work also with the University of Miami. In 2010 – since 2010, because we brought Julio Frank to the University of Miami as president. We were working before there –

before Julio arrived as president of the University of Miami. And also you can see WHO, and so on.

DR. RUIZ DE CHÁVEZ: Something that you know was with us and we were working with him, we were very happy with Steve Hauser, and we are – thank you, Steve. And it was the publication. It is also online. And people came from Caribe [the Caribbean], Latin America, and U.S., of course, and Canada.

This was in the left the national – the Global Summit, and which was – we had nearly 60 countries, and the right one was the World Congress that we have 1,200 people.

[Christine Grady, a Commission Member, notices pictures of herself at speaking event on Dr. Ruiz de Chávez' presentation slide and makes an inaudible comment. Dr. Ruiz de Chávez responds.]

DR. RUIZ DE CHÁVEZ: I know that.

DR. RUIZ DE CHÁVEZ: In the left also, you are in the Global Summit participating, and also in the World Congress.

DR. RUIZ DE CHÁVEZ: You have to discount the time that I am losing because I – next slide, please.

DR. RUIZ DE CHÁVEZ: We worked together with Xóchitl Castañeda from the University of California on this topic of migration, and we took this presentation also to the Global Summit in Berlin. It was a hard topic in Berlin, but it was a lot of people looking at it, other committees, of our approach.

And I think that – next slide, please. No. La siguiente, por favor. ["The next (slide), please."]

(Laughter.)

DR. RUIZ DE CHÁVEZ: This is – well, you see, the National Commission, and when in November, France has this [referring to the recent terrorist attacks in Paris], we put the colors of France. In Belgium, we put the colors of Belgium as solidarity of the National Commission of France and Belgium.

This is my presentation.

(Applause.)

DR. WAGNER: Our final speaker of this panel is Patricia King. Pat is the Carmack Waterhouse Professor of Law, Medicine, Ethics, and Public Policy at Georgetown University Law Center, and an Adjunct Professor in the Department of Health Policy and Management in the School of Hygiene and Public Health at Johns Hopkins University.

Professor King graduated from Harvard Law School and is a Member of the National Academy of Medicine, a Member of the American Law Institute, a Fellow of the Hastings Institute, and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health, and stem cell research.

DR. WAGNER: She has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects – excuse me, Human Subjects of Biomedical and Behavioral Research; the President's Advisory Committee on Human Radiation Experiments; the National Institutes of Health's Embryo Research Panel; and Ethics, Legal, and

Social Issues Working Group of the NIH's Human Genome Project; and the NIH's Recombinant DNA Advisory Committee.

She is also a past member of the Harvard Corporation, which we know to be the governing board of Harvard University.

Pat, welcome. It's good to have you here.

DR. KING: Thank you so much for inviting me. It is a pleasure to be here. And, what I have to say now following the three prior speakers, is almost nothing because they have covered a lot of the territory.

Nonetheless, I'll go forward. What I would like to do today is to talk about what I think made the National Commission successful, and I would then like to turn to what I'd like to recommend be covered by future commissions. The two are linked – lawyers, due process, as well as substance – and I think there are certain aspects of the National Commission and the way it was set up that made it successful. So, I'll start there.

DR. KING: I have served on way too many commissions and bodies. There is one that I omit, but I'm going to reference it here because I'm going to come back to it, and that is – I was briefly a member of the President's Commission for the Study of Ethical Issues in Medicine and Biomedical and Behavioral Research, which was a very different type of commission.

I left that commission because I got a government appointment, and government officials couldn't serve on that body. But, for the time that I was there, I formed some very definite opinions about that as well.

DR. KING: So, what made the National Commission successful? Well, it always helps to be first so we could make it up as we went along. And we did, and I think some of this is important to recall. We elected our own Chair from the existing membership. We replaced the assigned Executive Director for the National Commission, who was also a part of NIH, and selected another Executive Director because we thought there was a potential conflict. I think those kinds of actions helped us, but I admit that they were very risky actions because it could have gone in the wrong direction trying to replace midstream.

And why do I talk about that? Because Ruth talked about power, and so, a couple of things that I'm referring to here are about ways of asserting power because Ruth is right. You don't want to do this work unless you make a difference, and you don't always have that in your control. But, asserting your power in a positive way often leads to success.

The National Commission, as many have talked about, had a very rare sort of power. We had what you would call an action-forcing power and that is, the federal government had to respond to us. There is no greater power, though they can respond negatively.

DR. KING: They had to receive all of our reports and to explain publicly why they were not accepting our recommendations. I doubt that any other commission is going to have that in the future, so Ruth's point about figuring out ways to achieve some of the same consequences is really critically important.

And I would point out that the federal government did, indeed, reject our recommendations with respect to the institutionalized mentally ill. So it worked both ways. But, they accepted our recommendations with respect to subjects of research virtually across the board, although we had

some bad reports. But, with respect to children, fetuses, prisoners, they accepted our recommendations.

DR. KING: We also had a specific integrated mandate. I think that's really important. Otherwise, my experience is people like to add to your agenda. So, our mandate frame was basically research subjects. There were all kinds of different subjects, but the basic framework was to take a hard look at what was happening in federally funded research.

And, so it allowed us to learn, have a frame in which we could learn from report to report about how to think about this huge issue, which was the collection of people who participate in research.

It helped that Congress and I had forgotten to mention that, that we were the only one created by Congress, which is very important. They did something quite important, I think in retrospect, though it was really hard to live through, and that is that we were required to issue a report on fetuses in three months, 90 days. We were a group of people who had never seen each other, but that applied to most of us. We did it. And doing it, having something to focus on to get us moving quickly, worked.

DR. KING: During that process, we bonded. During that process, we learned how to have respect for people that we fundamentally disagreed with. We learned to listen carefully. And I might say, we bonded. I don't know what you've done, but every Friday night when the Commission met, once a month, we all went out to dinner. We all had drinks and went out to dinner. And we did meet every month, sometimes twice a month, from '74 to '78 (1974 to 1978). So, we were a committed group of people, which also helps in terms of success.

DR. KING: We were the first major commission to operate under the Federal Advisory Committees Act, and that was very important. If you haven't discussed abortion in public with an audience, then you have not lived. And I hope you never have to do it. But we were the first to – and we had to learn how to discuss very controversial issues with everybody sitting and looking at us.

We had a diverse membership, and I'm going to pause here. Basically, we came from the fields of medicine, psychology, law, and philosophy. We were 11 people, and one of the regrets that I have about our structure is that I think that our membership was not diverse enough, and I know that some of the subsequent commissions have not been diverse, either, in the sense in which I'm going to discuss.

DR. KING: I was a government employee about to leave HEW when I got asked to join the National Commission. [HEW is an abbreviation for the *United States Department of Health, Education, and Welfare*, the former name of the U.S. Department of Health and Human Services.]

DR. KING: I didn't know anything about ethics. I didn't know anything about science. I didn't know anything but civil rights law.

This statement gives me some pause, but what I want to say is that was an asset for the Commission in the sense that people who came from the invested fields had formed their views about some of the issues. Those of us who came without expertise, hopefully some sense, I think made a difference in a public body like that. That's my first point.

DR. KING: My second point is that we – it would have been wonderful if we had had an historian and a social science person on the Commission. One of the things being on a bioethics

commission does – I should say Ruth got a historian for ACHRE. One of the things that the National Commission missed, or didn't get to, there was nobody to give us a social context for what we were doing. And the absence of a social context, I think, was an unfortunate liability. And let me give you a for example.

The Tuskegee experiment was one of the reasons that we had the National Commission. There were several reasons. Fetuses were another. But we didn't talk about the issues ever in research raised by a situation like Tuskegee. And that meant there was an absence of expertise. I may be wrong, but I certainly think people from the social sciences would have pointed out a lot of those kinds of questions about power, about discrimination, et cetera.

So, I think who is a member of a commission is really critical, and you need a really good balance. Continuity, I thought, was critical because we lost two members, who died, but they were never replaced, and we were together for the entire time.

DR. KING: I think one of our strengths was that we reached consensus. We worked so hard at it and I think people don't think about these things. You have to work at working hard together, and that's very important.

And, finally, let me say we were lucky to have a very focused audience. The people who followed us day to day were people who had special interest in the subject, but it was basically the federal science establishment and Congress. So, it's easier than when you have to satisfy broad groups, then you can be more focused.

Tom's already said how many reports we issued, and of course we are best known for the Belmont Principles. So, I won't mention those two things because they've already been discussed.

DR. KING: I think we avoided potential catastrophes. I've served on other groups where there are catastrophes. One of them is that we avoided capture by any group. If you've got capture – Jim Childress and I were on the fetal tissue transplantation committee. What a disaster. Because there was no possibility for agreement, even around the edges, and I sort of call that capture.

And it's important to say – and I think this will be true for all commissions – there are some things we did that nobody really cared about, and that comes with the territory.

Where do I think we need go in the future? I have spent most of my time in science, science research, breakthrough technologies, talking about the ethical issues. And in reflecting on that history and the National Commission, I've come to my own realization, anyway, that it's time to return to what the second presidential commission accomplished. They worked in medicine and health, not research. Medicine, health, dying, decision-making, et cetera.

DR. KING: It's time to have, I think, a commission that works in health. I think it's particularly true now because we are in a society and a world that is focused on inequalities, a country and a world that's focused on justice, not only in the sense in which it is discussed in the Belmont Report, but justice in the sense of thinking about human rights, thinking about disparities, thinking about justice in – I think of it as justice in terms of those who have and those who don't. And there are a number of issues within that frame of thinking about health that would be well-served if there were a national commission to focus attention on those issues.

Every day when I pick up the paper, I see one. I saw one this morning. I saw one this morning in the papers about the fact that we send children and the disabled and those who have no one to take care of them to institutions where they need not be except for the fact that we have not thought about the issues outside of institutions.

DR. KING: That was my latest example, but I have many more. It would be like the National Commission in terms of groups. And there are many people already dealing with these issues, but none would have the prestige of a presidential commission. And my bottom line is we've done a lot for basic science. We've done a lot for the people who participate in basic science. It's time to think a little broader in terms of what the impact can be in a broader community.

I'll close there.

(Applause.)

DR. WAGNER: Thank you all. What a wonderful breadth of perspectives. We could ask questions, and perhaps we will in this little Q&A session, everything ranging from your point on justice in healthcare, which actually links, Tom, to what you were saying about human rights base versus utility. I appreciate also the thoughts about how deliberations might be improved in future by the configuration of future groups.

I have a quick question, and it went to the impact point that all of you made. And this particular group, our particular group, has been very focused on all of its reports, and now a very specific report on the education side.

DR. WAGNER: I would be interested, Dr. Ruiz de Chávez, your slides showed that you have a relationship with, I think it's the National Association of Universities and Higher Ed. Institutions. You also talked about relationships with professional societies, and presumably around continuing education.

DR. WAGNER: Are these formal links in Mexico? And, to the other panelists, are there links such as this that we ought to be recommending for, again, as another dimension of impact, impact not just solely on policy but impact on public and profession? So, I'd be curious.

First of all, what are your links?

DR. RUIZ DE CHÁVEZ: Well, if I understand, it is for us very important because we are not able to assist, for example, the strengthening of the committees, and the universities are very important for us in order to develop short courses for the committees. Or, something which is very important, we think that it's the best way to approach, as Patricia was saying to, to the society to teach, to use universities not for the academic approach, which is very important to research, but they need to be close to society to teach why it is so important, bioethics.

DR. RUIZ DE CHÁVEZ: Bioethics is for the people. It's for the people who go to the hospital, and sometimes they don't know what to do. Even between doctors and nurses, or even the family or the relatives with the doctors, and so on. And it's very important to – just to reflect, to think about what is the best way to approach any kind of –

DR. WAGNER: Certainly this Commission would agree with that. But, Ruth, you talked about the creative mechanisms of power. Are there similar powers that the Commission ought to be looking at in order to have outreach through these educational and professional pathways?

DR. FADEN: I think you've got two sitting at the end of the table, in this sense, and everywhere in the Commission. In the experience of ACHRE, the Advisory Committee, there was a phrase we ended up using at the end. It was something like, we had a healthy skepticism about rules and regulations, and a renewed respect for standards, culture and leadership. And that – I'm sorry.

DR. GUTMANN: I just want to say we learned from you there. So, we actually had a subsidiary principle of regulatory parsimony which, given what's happened since your commission is, I think, even more important. But please, go –

DR. FADEN: I'm delighted. Part of that came from realizing that there were many rules on the books that would have prohibited almost anything that happened. And this is true. There were plenty of rules, but there was no permeation to use that word of the values that the rules were intended to instantiate in the culture and practices of the professionals and the political people who were in powerful positions.

So, the route to that is very different, and is, I think, exactly why you've landed, I'm guessing, or one of the reasons why you've landed on putting so much emphasis in terms of education and training in the next generation.

DR. FADEN: One of the things we – we didn't have action-forcing in our mandate. But President Clinton, when he received our report, issued an order requiring the agencies to respond to our recommendations within one year. And there was a document, and every one of our recommendations has a response or exception or rejection.

And so this is still possible. Right? In other words, this is something that the Administration could do in response to your – when you are 'sunsetted', all right, or whatever term you choose to use.

And one of my – I think all of us will go back and look at this systematically in October, but there were many recommendations we made that were translated pretty quickly, accepted; others that were outright rejected; and some that I wish had been taken up more robustly. And I think part of the problem why they weren't is they weren't specific enough, and they were in the

leadership education area. So, if I had a recommendation, I would – this is the kind of recommendation you make in public health – make your objectives, make your recommendations, as specific as possible, as particular as possible, so that it's less likely for people who respond to respond in a way that is like vaguely accepting, but then you really don't have a metric or a way to say that they in fact have adopted the recommendation in the fulsome way in which you intended it.

And the education leadership area is one where – huge, huge, unopened for them.

DR. BEAUCHAMP: I can't put a pretty package together, given your question, but I might say a couple of things. You were talking about links to educational institutions, and there already are a lot of links between educational institutions and the government in bioethics. For example, sitting around your table here are links.

One of the things that have concerned me is the absence in bioethics – a virtually complete absence – of any interest in links to corporations. I do not understand it, and I think it's a matter of appalling prejudice that that's the case.

Some of you may know I worked for 15 years as an advisor to Eli Lilly, a pharmaceutical company. The bioethics that was done there is as good as the bioethics that's done in universities, just to make a grand generalization. It was very serious stuff.

When I tell people, or they ask me because they know about it, that I did this kind of work, they're appalled that I would have this kind of link to a corporation as if it's somehow dirty to get down and be involved.

And that's something that I think needs a serious correction. I'm not sure at the level of government because I don't know enough, but certainly at the level of educational institutions. There's an odd thing that I've discovered, which is that educational institutions have serious prejudices about the kind of science that's done in corporations. But, when you talk to people in corporations, they'll point out that a lot of the research that's done in universities is not as good or as productive as the kind of research that they do.

We need to stop this kind of stuff and get people in corporations interested in bioethics because there's a deep, deep need out there and the links really just are not being formed.

DR. GUTMANN: I wanted to pick up on Pat's – well, she began with a disclaimer. Actually, Pat, what you said I thought had enormous focusing value on some of the important dimensions. And I just want to highlight them and then ask a question about one or two of them.

Diversity of the – what makes for successful commission? The diversity of membership. You have to have the right kind of diversity for the charge. You have to take into account the social context. And I'm going to come back to that and how the social context – just to give you a sense of the question, so I'll – how has the social context changed? It has changed dramatically since the mid- and late 70's to now in the effectiveness of what kinds of communication, for example.

DR. GUTMANN: Then, continuity of membership – we've really experienced that, and how much of a difference. Being able to reach consensus – in a fractured political environment where there's gridlock in Washington, widely agreed upon that there is gridlock across all of the polarized parties, if a group of – and two of our members are missing and we, alas, really mourn the loss of John Arras, and we miss Lonnie Ali.

If this group can't reach consensus on things that are totally fractured in a fractionated society, what hope is there for making – pushing policy, on the policy issue for it? That's different from deep philosophical issues. So, reaching consensus.

DR. GUTMANN: Knowing who your constituency is: It may change, but actually having some sense of it. And then, I love the avoiding catastrophes. Those are, I think, very important rubrics for us to reflect on.

So, I'm going to come back just to the – How is the social context different in relevant ways? You've all reflected on what you did in the past, decades ago. Do you think about how the social context, think about doing what you did then and also how the charges would change? Because we've thought about that and we have to continue to think about that.

So, who would like – I'd begin with Pat because you reflected on how important it is to know the social context, and I totally agree with that.

DR. KING: Well, I guess I can describe what we missed pretty clearly. What we missed pretty clearly was the fact that there were women. We missed we just went right by Tuskegee. We went right by poverty, class, all of which and I can look back on. I actually thought about women and minorities at the time, but that's because I had been in a civil rights organization.

I think today's social context is probably as embittered as any time – you'd have to go back a long time, 19th century, to get a comparable situation. But, I still think that a group can talk about tough issues if you give some thought to how you can establish trust. Bonding is what I call it.

DR. KING: The National Commission had pro-choice people, pro-life people, disciplinary disputes, but I think we got to know each other. And, because we set that kind of example, it worked. I think the current context is marked by inequalities of all sorts. I think the current – and I don't think just the United States.

DR. GUTMANN: International, yes.

DR. KING: Internationally. And so one of the things and while it is important to have experts and professionals – this is my other point. While it's important to have experts, professionals, it is important to bring in people excellent people, I hope. I'm not saying that you're departing from the expert testimony but somebody who's not spent a lot of time thinking and having a fixed view of what the issues are, who's willing to give the time and effort to coming up to par. You just need to not talk among yourselves in the old-fashioned way. So, anything that can disrupt that a little bit, I think is a good thing. And I'll stop.

DR. GUTMANN: No, that's terrific. That's really helpful.

DR. WAGNER: On just that point –

DR. GUTMANN: Manuel?

DR. DE CHÁVEZ: Sorry to interrupt you. I think it's a very important issue, and the social context, for example, in speaking about Mexico, is not the same in the North and the South, and the vulnerability is different in the North and the South. And I think that also that [women's] rights is quite different in some areas of Mexico.

And as you were saying, the cultural approach to this is [totally] different. And I think that's a reason because we think that the best way to deal with these social context is that each state has its own commission, you know, and to deal with these social differences in some way.

DR. WAGNER: Let me go just to Nelson and Nita because then we're going to have – if others have questions you can do it in the larger roundtable.

DR. MICHAEL: I'll be quick. And Tom, you already set me up because you mentioned the issue of corporations. Even before your remarks, I was going to ask what your views were because you have to remember who your constituents are.

Largely, these commissions are formed to inform government. And, when we struggled after the Guatemala exposures that preceded Tuskegee, and arguably were far worse, we really began to struggle with it with the issues of how our recommendations were going to impact non-federal funded research, and especially a significant amount of work that's done overseas by corporations.

Now, I'm in the business of making vaccines, HIV and more recently Ebola and Zika and MERS, so, I understand the powerful importance of corporations. And we even had corporations come and testify with us. But, I still felt we kind of missed the mark in some way because again, our primary responsibility is to report to the President.

So, how did you deal with that sort of dichotomy? You are trying to speak to a general audience and yet, at the end of the day, you're writing a report to the President of the United States, not to Merck or Sanofi Pasteur.

DR. BEAUCHAMP: Is that a question directed at me?

DR. MICHAEL: You started it.

(Laughter.)

DR. BEAUCHAMP: I'm not sure what to say about this. I do think – I don't know if Patricia would agree with me about this – we had an unusual power, as she pointed out. We knew that what we were doing were very likely to become federal regulations. So, there's a way in which what you say is correct.

However, I don't think we ever thought that it was just a matter of informing the government, and then the government would do this, that and the other kind of thing. We thought of it as a way of making a difference in institutions, and I still think of it in that way.

IRB's a good example, a constant focus on what IRBs should be doing and what they shouldn't be doing and what was permissible and so on. Not because, we wanted the federal government necessarily to execute some plan for IRBs, but to get out our thinking about what the constituency and structure and work of IRBs should be, as well as to the extent that which they are failing or they were succeeding and so on. So, I thought there was always a larger purpose in what we were doing.

DR. KING: I can respond to the question about corporations. And Tom was right. I would disagree with him. I don't think I'd ever go work directly with corporation. But I think it is important. Our economy is – an economy, it is organized. It has many players.

But I certainly have worked with corporate officials in IOM, and I thought it was a good thing that we were working the corporate officials, that we were getting their areas of expertise. I don't

like working for a company, but getting their areas of expertise, I think, is undoubtedly important if you want to be practical, have a practical focus in your work.

So maybe there's a way to construct those kinds of inputs, either in a commission itself or in people who come and testify, or that you consult about a special problem. I think what they know is very important for the rest of us to understand.

DR. FARAHANY: Mindful of the fact that we're moving to roundtable, I'm just going to have a couple of reflections because this was such a rich and wonderful panel. First, I'll say I wish that we had had the ability to reflect in the beginning, the first time, rather than now, because I think there are some really useful learnings here that I hope could start the next commission, whatever form that may take.

DR. FARAHANY: And so just a few of those. One is, I think, your reflections on the ideas that maybe the next commission needs to take on more systemic and structural issues rather than just kind of topical issues, which I think is consistent with some of what Tom started us with, which is to look at other frameworks as well if you're thinking about systemic issues one, of course, that we've heard at some of our past meetings, but and we've certainly made some discussion of in our reports but I think requires much greater inquiry and focus of the kind of nature that you did with the Belmont Principles as a human rights framework for bioethics.

DR. FARAHANY: It's, I think, extraordinarily neglected. It's really kind of the next place we need to go, particularly if we're thinking about this at an international level.

I think some of the other issues like accountability and power, that would have been great in the beginning, which is – I think we made some efforts for accountability. But even just those types of past practices, I think, were so enormously useful. We certainly did in synthetic biology ask

for, after 18 months, for some sort of response. But it's different than having the President issue a requirement.

DR. FARAHANY: But it's also different than publically having a scorecard and a report card about what's happening and making that something that is a shaming device and also an accountability device, which I think is incredibly useful.

On the issue of corporations, I think it's right that there are other perspectives that need to round out the commissions. A historian of science, I think, would be extremely valuable.

DR. FARAHANY: A greater emphasis on corporate responsibility and the role of corporations: We've encountered that a lot with especially direct-to-consumer technologies and thinking about the role of corporations. One thing that heartens me is that particularly within the genomic space I've heard from quite a few companies recently who are forming ethics boards. And I think that's terrific.

DR. FARAHANY: Now the cynic in me is they just want an endorsement so that they can appear ethical. The more optimistic side of me is that they're taking seriously the issues because they recognize that they are at the center of it and they have ability to really influence public conversation and dialogue, and that they're bringing in quite thoughtful people.

And so, I think modeling what bioethics commissions, particularly as you modeled for us what's happening in Mexico that is a more distributed model across corporations through ethics boards through state commissions, which we have some form of, but figuring out how all that might be integrated under a national bioethics commission, would be really useful.

DR. FARAHANY: And, so while we're just at the point of reflecting for the next one, and one of the things we've lamented is the fact that a lot of this material is lost when you get to the next commission because there is no kind of continuing commission, I think if there's some way that we can capture some of the wisdom here to be able to have the next iteration launched in a more successful way, that would be great.

So I hope we can capture all of the things you've said. But if we distill it, as I know Amy will make you do, as to the single kind of idea that you might want to carry forward for the next commission, I'll look forward to those comments and thoughts at the roundtable discussion.

DR. WAGNER: As we shift to our next group, you guys, I think, can just stay put. But, you have to listen to our applause and thanks.

(Applause.)